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(71) Applicant: **C.R. BARD, INC** [US/US]; 730 Central Avenue, Murray Hill, NJ 07974 (US).

(72) Inventors: **COX, Jeremy, B.**; 685 Eighth, Avenue, Salt Lake City, UT 84103 (US). **SOUTHARD, Glen, E.**; 120 Paradise Road, Park City, UT 84098 (US). **LINDEKUGEL, Eric, W.**; 1381 Hudson Avenue, Salt Lake City, UT 84106 (US). **MESSERLY, Shayne**; 172 East 650 South, Kaysville, UT 84037 (US). **FARNWORTH, Charles**; 3322 Fitch Road, Riverton, UT 84065 (US).

(74) Agent: **WIGHT, Todd, W.**; Rutan & Tucker LLP, 611 Anton Boulevard, Suite 1400, Costa Mesa, CA 92626 (US).

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(54) Title: RUGGEDIZED ULTRASOUND HYDROGEL INSERT

(57) Abstract: A ruggedized hydrogel product that is formulated to withstand the effects of high-energy sterilization procedures, such as gamma beam and electron beam sterilization, without significant structural degradation is disclosed. This enables the hydrogel product to be suitable for use in medical applications where sterile components are required. In one embodiment a ruggedized hydrogel product is disclosed and comprises a gel component, water for hydrating the gel component, and at least one free radical absorber component that is capable of absorbing free radicals produced when the hydrogel product is sterilized via a high-energy sterilization procedure. The free radical absorber component in one embodiment includes potassium metabisulfite and ascorbic acid. The ruggedized hydrogel product can be included with an ultrasound probe to provide an acoustically transparent interface between the probe and the skin of a patient.



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**RUGGEDIZED ULTRASOUND HYDROGEL INSERT****CROSS-REFERENCE TO RELATED APPLICATIONS**

[0001] This application claims the benefit of U.S. Provisional Application No. 61/563,382, filed November 23, 2011, and titled "Ruggedized Ultrasound Hydrogel Insert," and U.S. Provisional Application No. 61/556,626, filed November 7, 2011, and titled, "Systems and Methods for Ultrasound-Based Pneumothorax," each of which is incorporated herein by reference in its entirety.

**BRIEF SUMMARY**

[0002] Briefly summarized, embodiments of the present invention are directed to a ruggedized hydrogel product that is formulated to withstand the effects of high-energy sterilization procedures, such as gamma beam and electron beam sterilization, without significant structural degradation. This enables the hydrogel product to be suitable for use in medical applications where sterile components are required.

[0003] In one embodiment a ruggedized hydrogel product is disclosed and comprises a gel component, water for hydrating the gel component, and at least one free radical absorber component that is capable of absorbing free radicals produced when the hydrogel product is sterilized via high-energy sterilization procedures. The free radical absorber component in one embodiment includes potassium metabisulfite and ascorbic acid.

[0004] The ruggedized hydrogel product can be included with an ultrasound probe to provide an acoustically transparent interface between the probe and the skin of a patient. In one embodiment, the hydrogel is configured as an insert included with a cap that can be removably attached to the probe. In another embodiment, the hydrogel is configured as a slab that is attached to the bottom of a pancake probe. In addition, other configurations can also be employed.

[0005] These and other features of embodiments of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of embodiments of the invention as set forth hereinafter.

**BRIEF DESCRIPTION OF THE DRAWINGS**

[0006] A more particular description of the present disclosure will be rendered by reference to specific embodiments thereof that are illustrated in the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope. Example embodiments of the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0007] FIG. 1 is a perspective view of a cap for an ultrasound probe including a ruggedized hydrogel insert according to one embodiment;

[0008] FIGS. 2A-2C are various views of a tray for housing the cap of FIG. 1 according to one embodiment;

[0009] FIG. 3 shows the cap of FIG. 1 disposed in the tray of FIGS. 2A-2C according to one embodiment;

[00010] FIGS. 4A and 4B are exploded front and side perspective views of an ultrasound probe including the cap of FIG. 1 according to one embodiment;

[00011] FIG. 4C is an assembled front perspective view of the ultrasound probe and cap of FIGS. 4A and 4B according to one embodiment;

[00012] FIG. 5 shows an ultrasound system including a probe for use with a patient according to one embodiment;

[00013] FIGS. 6A and 6B are various views of an ultrasound probe including a ruggedized hydrogel product according to one embodiment;

[00014] FIG. 7 is a top view of an ultrasound probe including a ruggedized hydrogel product according to one embodiment; and

[00015] FIG. 8 is a flow diagram showing preparation and dispensing of a ruggedized hydrogel product according to one embodiment.

### DETAILED DESCRIPTION OF SELECTED EMBODIMENTS

[00016] Reference will now be made to figures wherein like structures will be provided with like reference designations. It is understood that the drawings are diagrammatic and schematic representations of exemplary embodiments of the present invention, and are neither limiting nor necessarily drawn to scale.

[00017] For clarity it is to be understood that the word "proximal" refers to a direction relatively closer to a clinician using the device to be described herein, while the word "distal" refers to a direction relatively further from the clinician. For example, the end of a catheter placed within the body of a patient is considered a distal end of the catheter, while the catheter end remaining outside the body is a proximal end of the catheter. Also, the words "including," "has," and "having," as used herein, including the claims, shall have the same meaning as the word "comprising."

[00018] Embodiments of the present invention are generally directed to a ruggedized hydrogel product that is formulated to withstand the effects of high-energy sterilization procedures, such as gamma beam and electron beam ("e-beam") sterilization, without significant structural degradation. This enables the hydrogel product to be suitable for use in medical applications where sterile components are required.

[00019] For example, the ruggedized hydrogel product can be included in one embodiment for use with an ultrasound probe. Particularly, the hydrogel product in one embodiment is positioned between a head portion of the probe and the patient's skin so as to act as an acoustically coupling interface during use of the probe in imaging subcutaneous tissue of the patient. This enables ultrasound signals emitted and received by the probe head to be efficiently transmitted between the head and the patient's body through the hydrogel, thus improving the quality of images produced by the ultrasound signals.

[00020] In addition, the hydrogel includes a substantial amount of water, which is exuded therefrom during use, thus providing a low friction interface that enables smooth sliding movement of the probe atop the skin. The relatively high water content of the hydrogel also mimics the composition of tissue in the patient's body, thus providing a relatively uniform medium for the transmission of ultrasound signals into and out of the body. Moreover, the hydrogel as disclosed herein is solid but compliant so as to conform to

variations in the skin surface, thus enhancing the ability to maintain acoustic coupling between the probe head and the patient's body when the probe is slid over the patient's skin.

[00021] As mentioned above, the hydrogel product is both biocompatible and sterilizable so as to be usable in standard clinical environments. In particular, the hydrogel formulations disclosed herein can be subjected to standard sterilizing procedures, such as gamma beam and electron beam sterilization, without liquefying or otherwise physically degrading. This enables the hydrogel to successfully and safely undergo sterilization procedures together with other components to be sterilized, such as within a kit for instance, which increases manufacturing efficiency. In addition, the hydrogel can be configured to withstand other forms of sterilization/sterilizing materials, including ultraviolet light, hydrogen peroxide, ozone, and corona discharge treatment, in one embodiment. As used herein, "hydrogel" is understood to include a polymer network dispersed in water, often exhibited as a semi-solid gel.

[00022] Reference is made to FIG. 1, which depicts a cap 10 for use with an ultrasound probe, such as the probe 30 shown in FIGS. 4A-4C, according to one embodiment. The cap 10 is configured to operably attach to the probe 30 in a snap-fit or other suitable arrangement so as to cover at least a portion of a head portion 32 of the probe. Further details regarding the ultrasound probe 30 are given further below.

[00023] A hydrogel insert 12 including a hydrogel product configured in accordance with one embodiment is included with the cap 10. As shown in FIG. 1, the insert 12 is disposed in an opening 14 defined in the cap 10 so as to be secured in the configuration shown. The distal end of the insert 12 defines a concave shape to act, in one embodiment, as a standoff component for providing a physical separation between the ultrasound probe 30 (FIGS. 4A-4C) and the patient's skin, thus preventing compression of superficial veins beneath the skin and therefore enabling suitable imaging thereof. In the present embodiment, a fixture 16 is included on the cap 10 for receipt of a needle guide to help guide a needle into the patient after a suitable vessel has been found via ultrasound imaging. Further details regarding the cap and needle guide can be found in U.S. Application No. 13/206,396, filed August 9, 2011, and entitled "Support and Cover Structures for an Ultrasound Probe Head" (atty. docket no. 0112P2), and Application No. 13/335,587, filed December 22, 2011, and entitled "Selectable Angle Needle Guide" (atty. docket no. 0157P), each of which is incorporated herein by reference in its entirety. It should be noted that the discussion herein

concerning the hydrogel component and its use with an ultrasound probe is merely an example of one implementation thereof and should not be considered limiting of the range of possible uses for the hydrogel product.

**[00024]** FIGS. 2A-2C show a tray 20 that serves as a mold in the present embodiment for forming the hydrogel insert 12 of FIG. 1, as will be described. The tray 20 includes a suitable material such as a thermoplastic and defines a cavity 22 for receiving various components therein. Specifically, a cap cavity portion 24 is defined in the cavity 22 and is shaped to removably receive therein the cap 10 of FIG. 1. A convexly-shaped hydrogel insert cavity portion 26 is defined within the cap cavity portion 24 and is shaped to provide a mold surface and volume for defining the hydrogel insert 12 when the insert is manufactured, as will be described further below. Also included is a cavity area 28 adjacent the cap cavity portion 24 to provide a space where a needle guide can be disposed if attached to the cap.

**[00025]** FIG. 3 shows the cavity 22 of the tray 20 with the cap 10 disposed in the cap cavity portion 22 thereof. With the cap 10 so positioned a volume is defined, as mentioned, proximate the distal end of the cap 10 and the hydrogel insert cavity portion 26 in which the hydrogel product can be disposed and cured, as discussed further below, in order to form the hydrogel insert 12 in an attached configuration with the cap, as seen in FIG. 1.

**[00026]** FIGS. 4A-4C show the manner of attachment of the cap 10 to the head portion 32 of the ultrasound probe 30. Surface features on the cap 10 and the head 32 are included to enable the cap to be removably attached to the head in a friction fit arrangement, though other attachment schemes may also be used. This places the hydrogel component of the insert 12 at the distal end of the probe 30 to provide an ultrasonically transparent interface between transducer elements disposed in the probe head 32 and the patient's skin. Again, the probe, the cap, and the manner in which the hydrogel component is configured and used can vary from what is shown and described herein.

**[00027]** As mentioned, the hydrogel product of the insert 12 of the cap 10 is used in medical applications to assist with ultrasonic imaging procedures, such as imaging a subcutaneous vessel in preparation for insertion of a catheter, needle, or other medical device therein. As such, the cap 10 and accompanying hydrogel insert must often be sterilized prior to use so as to prevent transmission of microbes, diseases, viruses, bacteria, and so forth. In

the present embodiment the hydrogel product is formulated so as to withstand high-energy sterilization procedures that are typically used to sterilize medical devices and equipment.

**[00028]** Specifically, in one embodiment the hydrogel product from which the insert 12 is made includes a ruggedized formulation to provide the desirable qualities discussed above, including the ability to sterilize the hydrogel insert via gamma beam or electron beam sterilization procedures without causing physical degradation of the hydrogel. In one embodiment a hydrogel product is disclosed that includes various components, namely: a gel component to provide the gel structure itself, and water to hydrate the initially dry gel component. In accordance with the present embodiment, one or more free radical absorber components are also included in the composition to absorb free radicals that are produced in the hydrogel as a result of the high-energy sterilization process. Left unchecked, the free radicals cause undesired degradation and liquefying of the hydrogel, rendering it useless for the intended ultrasound-related uses discussed above. By including these absorbers in the hydrogel component, the free radicals are neutralized and are thus unable to cause hydrogel degradation.

**[00029]** According to one embodiment, non-limiting examples of free radical absorbers that can be utilized in the hydrogel of the insert 118 or other implementation include: glutathione, potassium metabisulfite, potassium disulfite, sodium formate, potassium formate, L-ascorbic acid, sodium citrate monobasic, L-glutamic acid monosodium salt, L-glutamic acid, catechin, organic compound-containing thiol, potassium iodide, vitamin E, cysteine, and other suitable absorbers including antioxidants employed in the food and cosmetics industry. Other salt forms of the above compounds can also be employed as suitable free radical absorbers. For instance potassium formate, a salt compound related to sodium formate, can be also be employed as a free radical absorber. In addition to the gel component and free radical absorber components, and water, other additive components can be included, including mixing aids, preservatives, etc.

**[00030]** In light of the above, in one example embodiment a hydrogel product includes the following composition:

**Table 1**

Category	Component	Quantity (percentage by weight, per each hydrogel unit)
Gel Component	Carrageenan Gum & Konjac Gum	About 2.09%
Free Radical Absorber	Potassium Metabisulfite	About 1.86%
Free Radical Absorber	Ascorbic Acid	About 0.025%
Additive	Isopropyl Alcohol	About 0.95%
Hydrating Medium	Deionized Water	About 95.07%

**[00031]** As seen in Table 1, the hydrogel component according to the present embodiment includes a gel component, two free radical absorber components, an additive, and water as a hydrating medium. The gel component in the present embodiment includes a hydrogel powder product, Stabilizer VPB-1, sold under the trademark COYOTE and manufactured by Gum Technology of Tucson, AZ. Comparable products are attainable from other sources. The Stabilizer VPB-1 powder gel component includes both carrageenan gum and konjac gum and provides the base for the hydrogel product. In one embodiment, the Stabilizer VPB-1 powder gel component includes a particle size of 90% minimum passage through a U.S. Standard 40 mesh sieve and can include potassium chloride and/or calcium chloride to provide standardization thereof.

**[00032]** The free radical absorbers of Table 1 include potassium metabisulfite (also known as potassium disulfite) and ascorbic acid, otherwise known as vitamin C. Each of these provides stability to the hydrogel component in absorbing free radicals created in the hydrogel during subsequent high-energy sterilization procedures. In the present embodiment, the potassium metabisulfite is initially in powder form and possesses a purity of greater than or equal to about 95%. The ascorbic acid is also initially in powder form and possesses a purity equal to or exceeding about 99%. In one embodiment, the above components can generally meet food or nutraceutical grade for use in the present hydrogel product

formulation. It is appreciated that the term "powder" herein can include various physical forms including particulate, granular, crystalline, crushed, etc.

[00033] The additive isopropyl alcohol ("IPA") in the present embodiment is of USP grade at a purity of equal to or exceeding 99%. The IPA aides in the dissolving and/or mixing of the other ingredients during hydrogel manufacture and also assists in neutralizing the scent of the hydrogel created by the free radical absorbers components. The water serves as the hydrating medium for the hydrogel product and subsequently provides the acoustic transparency necessary for the hydrogel product. In the present embodiment, deionized water is employed to provide an acceptable purity level. However, in other embodiments other forms of water with a low bio-burden or contaminant level can be employed, including sterile water, distilled water, filtered water, etc. Note also that the relative concentrations or inclusion of the various components can be varied from what is shown herein.

[00034] FIG. 8 provides a flow diagram 100 describing various stages of the preparation of the hydrogel product described herein. Though directed toward preparation of the hydrogel product having the formulation depicted in Table 1 above, the flow diagram 100 can also be applied to other possible hydrogel formulations, including those additionally described herein. At stage 102 the dry powder gel component, *i.e.*, the Stabilizer VPB-1 powder in the present embodiment, can be subjected to a pre-treatment heating process in order to reduce or eliminate any bio-burden, or presence of undesired biological entities (microbes, insects, etc.) In the present embodiment, the gel component is subjected to oven heating at about 120 degrees Celsius for about 4 to 5 hours.

[00035] At stage 106, a measured amount the pre-treated gel component is combined with measured amounts of the powder forms of the free radical absorber components 104, *i.e.*, the potassium metabisulfite and ascorbic acid in the present embodiment. In one embodiment, combining of these components is achieved via dry-mixing. In another embodiment, the powder components are merely combined without active mixing.

[00036] At stage 108, the combined powder from stage 106 is mixed into a vessel with measured amounts of deionized water, represented at block 110, and IPA, represented at block 112. In the present embodiment, the liquid IPA is added to the deionized water already present in the vessel before the dry-mixed powder is introduced into the vessel. In another embodiment, the IPA and water can be added at the same time. A mechanical mixer can be

used and the dry-mixed powder added slowly to the deionized water/IPA mixture to ensure dispersion and dissolving of the powder. The hydrated mixture ("hydrogel solution") is mixed for about two minutes after all the components have been added, in the present embodiment.

**[00037]** At stage 114, the hydrogel solution is subjected to a vacuum in order to reduce or eliminate any air bubbles in the mixture. In the present embodiment, the vessel used at stage 108 is a pressure vessel suitable for providing a vacuum so the hydrogel solution need not be transferred to another container. The vacuum is applied to the hydrogel solution a minimum of 10 minutes in the present embodiment so that all or most air bubbles trapped in the solution are released. The hydrogel solution can then be inspected to ensure it is smooth and substantially bubble-free. If not, the vacuum process can be repeated.

**[00038]** At stage 116 the hydrogel solution is heated to a temperature of about 85-90 degrees Celsius to keep it flowable in preparation for dispensing it at stage 118 and completing preparation of the hydrogel product. Of course, the heating temperature and other details of the procedure described herein can be varied in accordance with alterations in the hydrogel formula, intended use, etc., as appreciated by one skilled in the art. In the present embodiment, the hydrogel solution is loaded into a suitable pumping/dispensing device. Note that the dispensing device can also provide the needed heating of the solution shown at stage 116.

**[00039]** With respect to dispensing the hydrogel solution of stage 118, in one embodiment the solution is dispensed into a portion of the tray 20 shown and described in connection with FIGS. 2A-3. In particular, the hydrogel solution can be dispensed into the volume defined by the hydrogel insert cavity portion 26 when the cap 10 is disposed within the tray 20. As mentioned, the portion of the tray 20 that defines the hydrogel insert cavity portion 26 is shaped so as to impart the desired shape of the hydrogel insert 12 *{see FIG. 1}* when the hydrogel solution solidifies after dispensing.

**[00040]** In the present embodiment, the dispensing stage 118 includes placing the cap 10 (FIG. 1) in the cap cavity portion 24 of the cavity 22 of the tray 20 as shown in FIG. 3. In one embodiment a needle guide can be attached to the cap 10 prior to placing it in the tray 20; if so, the needle guide is disposed in the cavity area 28 of the tray cavity 22 when the cap is placed in the tray.

[00041] Once the cap is disposed in the tray, the cap 10 can be treated with a corona discharge treatment process to improve cap surface characteristics for receipt of the hydrogel solution that will solidify to form the hydrogel insert 12, FIG. 1.

[00042] After the corona discharge treatment the hydrogel solution, which is heated as previously described to maintain flowability, is dispensed from a suitable dispenser into the hydrogel insert cavity portion 26 of the tray cavity 22 in sufficient quantity to fill the cavity portion and backfill into the cap 10 via the opening 14 thereof a limited amount. Inspection after filling may indicate if air bubbles are present, the fill was insufficient or non-uniform or messy, etc. such that corrective measures may be taken.

[00043] After dispensing of the hydrogel solution into the cap 10 within the tray 20, the tray is left flat for at least 30 seconds in one embodiment to ensure that the hydrogel solution properly cures and solidifies into the hydrogel insert 12 (FIG. 1). As a portion of the hydrogel solution solidifies within the volume defined by the cap 10, attachment between the hydrogel and the cap is achieved. Note that the above-described procedures can be performed for each cap individually or in a batch process where multiple caps are filled with hydrogel solution. Note also that this is but one possible use for the ruggedized hydrogel; other hydrogel applications can also benefit from the principles described herein.

[00044] After curing of the hydrogel solution, the cap 10 and newly-formed hydrogel insert 12 can be sterilized by high-energy sterilization procedures without being removed from the tray 20. As described, because of its formulation the hydrogel product can withstand such high-energy sterilization without undesirably degrading and liquefying. In one example, the hydrogel product was exposed to about 30 kGy of ionizing radiation (gamma beam) sterilization without significant resultant hydrogel degradation.

[00045] Once sterilization is complete, the tray 20, including the cap 10 and attached hydrogel insert 12 disposed therein, can be packaged, stored, used, etc. For instance, the cap 10 in one embodiment may be attached to and used with an ultrasound probe, such as the probe 30 shown in FIG. 4C.

[00046] Below are various examples of preparations of a hydrogel product in accordance with embodiments of the present disclosure.

**Example 1**

[00047] A hydrogel product was prepared by first pre-treating about 100 grams of Gum Tech Stabilizer VPB-1 powder in an oven for about four hours at about 120 degrees Celsius. About 86.0 to about 89.9 grams of the pre-treated Stabilizer VPB-1 powder was then combined with about 75.7 to about 80.0 grams of potassium metabisulfite powder and about 1.01 to about 1.06 grams of ascorbic acid powder to form a hydrogel powder. The hydrogel powder was then mixed into an aqueous solution of about 4,000 ml of deionized water and about 40 ml of isopropyl alcohol for approximately two minutes after all of the hydrogel powder had been added to the aqueous solution. A vacuum cycle of about 10 minutes was then applied to the resultant hydrogel solution to remove any air bubbles. The hydrogel solution was then heated to a temperature of from about 85 to about 90 degrees Celsius and dispensed to a tray mold. The molded hydrogel solution was allowed to cure for about 30 seconds to form a completed hydrogel product. Note that the purities and other characteristics of the components of the hydrogel solution of the present example are similar to those described in the above discussion relating to FIG. 8.

**Example 2**

[00048] A hydrogel product was prepared by first combining dry powders of the following components in the specified concentrations (percentages are w/w- by weight) to form a hydrogel powder: gel component: kappa- carrageenan gum- about 0.7%; iota-carrageenan gum- about 0.3%; konjac gum- about 0.5%; potassium chloride- about 0.010% (about 8 millimolar ("mM")); free radical absorber components: L-ascorbic acid- about 2.5% (about 140 mM); potassium metabisulfite- about 1.33% (about 50 mM); preservatives: propyl 4-hydroxybenzoate- about 0.18% (about 1.0 mM); methyl 4- hydroxybenzoate- about 0.05% (about 0.4 mM). The hydrogel powder was then mixed into an aqueous solution to form a hydrogel solution. The aqueous solution included isopropyl alcohol comprising about 4% (about 500 mM) of the total hydrogel solution and deionized water comprising about 90.66% of the total hydrogel solution. The hydrogel solution was mixed for at least two minutes after all of the hydrogel powder had been added to the aqueous solution. The hydrogel solution was then heated and dispensed to a mold. The molded hydrogel solution was allowed to cure to form a completed hydrogel product.

**Example 3**

[00049] A hydrogel product was prepared by first combining dry powders of the following components in the specified concentrations (percentages are w/w- by weight) to form a hydrogel powder: gel component: kappa- carrageenan gum- about 0.7%; iota-carrageenan gum- about 0.3%; konjac gum- about 0.5%; potassium chloride- about 0.010% (about 8 millimolar ("mM")); free radical absorber components: L-ascorbic acid- about 2.5% (about 140 mM); glutathione- about 1.2% (about 40 mM); preservatives: propyl 4-hydroxybenzoate- about 0.18% (about 1.0 mM); methyl 4- hydroxybenzoate- about 0.05% (about 0.4 mM). The hydrogel powder was then mixed into an aqueous solution to form a hydrogel solution. The aqueous solution included isopropyl alcohol comprising about 4% (about 500 mM) of the total hydrogel solution and deionized water comprising about 90.56% of the total hydrogel solution. The hydrogel solution was mixed for at least two minutes after all of the hydrogel powder had been added to the aqueous solution. The hydrogel solution was then heated and dispensed to a mold. The molded hydrogel solution was allowed to cure to form a completed hydrogel product.

**Example 4**

[00050] A hydrogel product was prepared by first combining dry powders of the following components in the specified concentrations (percentages are w/w- by weight) to form a hydrogel powder: gel component: kappa- carrageenan gum- about 0.7%; iota-carrageenan gum- about 0.3%; konjac gum- about 0.5%; potassium chloride- about 0.010% (about 8 millimolar ("mM")); free radical absorber components: L-ascorbic acid- about 2.5% (about 140 mM); sodium formate- about 2.0% (about 300 mM); preservatives: propyl 4-hydroxybenzoate- about 0.18% (about 1.0 mM); methyl 4- hydroxybenzoate- about 0.05% (about 0.4 mM). The hydrogel powder was then mixed into an aqueous solution to form a hydrogel solution. The aqueous solution included isopropyl alcohol comprising about 4% (about 500 mM) of the total hydrogel solution and deionized water comprising about 89.76% of the total hydrogel solution. The hydrogel solution was mixed for at least two minutes after all of the hydrogel powder had been added to the aqueous solution. The hydrogel solution was then heated and dispensed to a mold. The molded hydrogel solution was allowed to cure to form a completed hydrogel product.

[00051] It is appreciated that in other embodiments the formulations identified in Examples 2-4, can omit the preservatives propyl 4-hydroxybenzoate and methyl 4-hydroxybenzoate from the hydrogel product formulation. In another embodiment, the free radical absorber ascorbic acid can be omitted from the hydrogel product formulation. In yet another embodiment, a suitable antibacterial/antimicrobial component could be added to the hydrogel formulation. IPA can be varied in concentration, such as from about one to about five percent by weight in one embodiment, or omitted from the composition in one embodiment. Indeed, if IPA is omitted from the hydrogel formulation, a small amount could still be added to an external portion of the hydrogel product post-manufacture so as to assist in masking any unpleasant smell of the hydrogel. Other aromatic or fragrant substances can optionally be used to mask the hydrogel odor. It is also appreciated that other gel components in addition to those listed herein can be employed, including polysaccharide-based gel components, for instance.

[00052] In yet another embodiment, it is appreciated that the hydrogel product can include a component to render the hydrogel bacteriostatic. In such a case, it may be chosen to not sterilize the hydrogel product, but rather rely on its bacteriostatic qualities. In one embodiment, a suitable substance, such as chlorhexadine, can be added to the hydrogel component to render it bacteriostatic. In this instance, the IPA could be included or omitted from the hydrogel formulation.

[00053] Reference is now made to FIG. 5 in describing one possible implementation of a ruggedized hydrogel product according to one embodiment. A patient 50 is shown undergoing an ultrasound imaging procedure with the use of an ultrasound imaging system 60, which includes a console 62 housing a display 64. An ultrasound probe 70, configured in accordance with one embodiment, is operably connected to the console 62 via a cable 72 or other suitable connective scheme and is positioned atop a portion of the patient's chest in order to provide ultrasonic images of a vessel or other subcutaneous features.

[00054] FIGS. 6A and 6B depict further details regarding the ultrasound probe 70 depicted in FIG. 5. The probe 70 has a general pancake shape and includes a flexible, annular perimeter portion 76 that is configured to be deformable. A reinforcement ring 78 is embedded within the perimeter portion 76 so as to limit the range of deformation for the probe 70. In one embodiment, the reinforcement ring 78 can be configured to maintain the

deformation of the probe 70 when deformed by a clinician in order to conform to a particular body contour of the patient.

[00055] A transducer 80 is included in the central portion of the probe 70 such that it is bounded by the perimeter portion 76. In the present embodiment, the transducer 80 includes polyvinylidene fluoride ("pvdf), which is a non-reactive and pure thermoplastic fluoropolymer that is also a piezoelectric material. As such, the pvdf material can serve as a transducer element for the transducer 80 in producing and detecting ultrasonic signals. Like the perimeter portion 76, the pvdf transducer is also flexible. The flexible nature of the perimeter portion 76 and the pvdf transducer 80 thus enables the probe to conform to body contours when it is placed upon the body of the patient.

[00056] FIG. 6B shows that the probe 70 further includes a hydrogel slab 90 that is positioned on a bottom surface of the transducer 80 so as to provide an acoustically transparent interface between the transducer and the body of the patient. In the present embodiment, the hydrogel slab 90 is manufactured as described herein so as to exhibit ruggedized characteristics and be able to withstand high-energy sterilization procedures. Thus, the hydrogel slab 90 of FIG. 6B shows one example of an optional use of the ruggedized hydrogel product described herein in addition to implementations already described.

[00057] FIG. 7 shows the pancake ultrasound probe 70 according to another embodiment, wherein the transducer includes a plurality of discrete transducer elements 94 that are physically and electrically isolated separated from one another by insulting dividers 96 of plastic or other suitable material. These and other transducer designs are therefore contemplated. In one embodiment, the probe 70 is employed in an A-mode ultrasound imaging setting to detect the presence of pneumothorax in a patient following the placement of a catheter or other device into the vasculature of the patient in the case where the device has punctured the lung. Differences noted in the A-mode ultrasound profile of the subcutaneous area of interest before and after catheter placement can indicate the presence of pneumothorax. Of course, the probe can be employed in other applications.

[00058] Embodiments of the invention may be embodied in other specific forms without departing from the spirit of the present disclosure. The described embodiments are to be considered in all respects only as illustrative, not restrictive. The scope of the

embodiments is, therefore, indicated by the appended claims rather than by the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

## CLAIMS

1. A ruggedized hydrogel product, comprising:  
a gel component;  
water for hydrating the gel component; and  
at least one free radical absorber component capable of absorbing free radicals produced when the hydrogel product is sterilized via one or more high-energy sterilization procedures.
2. The hydrogel product as defined in claim 1, wherein the at least one free radical absorber inhibits liquefying of the hydrogel product when subjected to high-energy sterilization procedures.
3. The hydrogel product as defined in claim 1, wherein the water includes deionized water and wherein the gel component further includes at least one of potassium chloride and calcium chloride.
4. The hydrogel product as defined in claim 1, wherein the gel component includes at least one of carrageenan gum, konjac gum, and locust bean gum.
5. The hydrogel product as defined in claim 1, wherein the water is included in an aqueous solution, the aqueous solution further including isopropyl alcohol.
6. The hydrogel product as defined in claim 1, further comprising a preservative that includes at least one of propyl 4- hydroxybenzoate and methyl 4- hydroxybenzoate.
7. The hydrogel product as defined in claim 1, wherein the at least one free radical absorber component includes ascorbic acid.
8. The hydrogel product as defined in claim 1, wherein the at least one free radical absorber component includes at least one of glutathione, sodium formate, potassium metabisulfite, potassium disulfite, sodium citrate monobasic, L-glutamic acid monosodium salt, L-glutamic acid, and catechin.
9. The hydrogel product as defined in claim 1, wherein the hydrogel product is employed as an acoustic interface between an ultrasound probe and the skin of a patient.

10. The hydrogel product as defined in claim 1, wherein the hydrogel product is suitable for sterilization with at least one of gamma beam and electron beam sterilization procedures.

11. A method for producing a ruggedized hydrogel product capable of withstanding a high-energy sterilization procedure, the method comprising:

combining into a mixture a gel component and at least one free radical absorber component;

hydrating the mixture to form a hydrogel solution; and

forming the hydrogel solution into a hydrogel product.

12. The method for producing as defined in claim 11, wherein hydrating the mixture further comprises hydrating the mixture with an aqueous solution including deionized water and isopropyl alcohol.

13. The method for producing as defined in claim 11, wherein combining the gel component and the at least one free radical absorber component further comprises combining dry powder forms of the gel component and the at least one free radical absorber component, the gel component including at least one of carrageenan gum and konjac gum.

14. The method for producing as defined in claim 11, further comprising heating the gel component in dry powder form to reduce a bio-burden of the gel component.

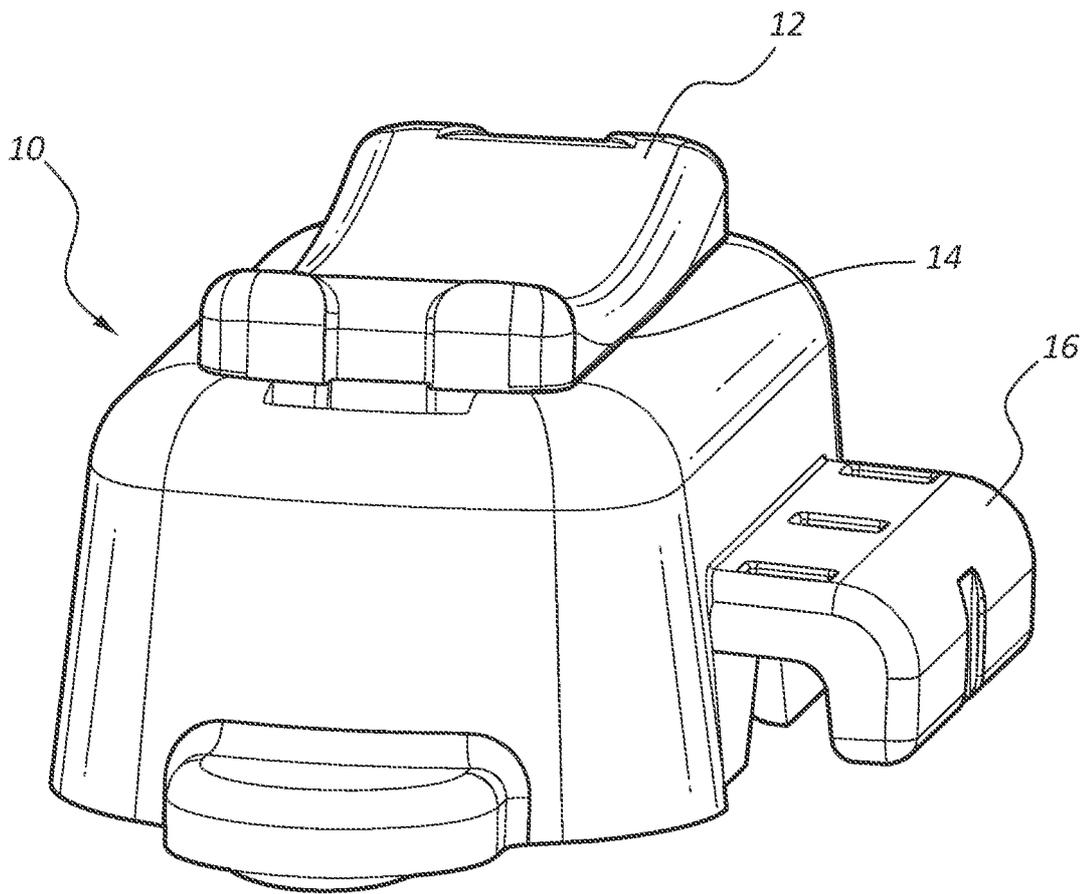
15. The method for producing as defined in claim 11, wherein forming the hydrogel solution further comprises dispensing the hydrogel solution into a mold.

16. The method for producing as defined in claim 15, further comprising dispensing the hydrogel solution into a tray mold including a cap for an ultrasound probe such that the hydrogel solution solidifies into a shaped hydrogel product attached to the cap.

17. The method for producing as defined in claim 11, further comprising:  
placing the hydrogel solution under vacuum to eliminate air bubbles; and  
heating the hydrogel solution prior to forming.

18. The method for producing as defined in claim 11, further comprising sterilizing the shaped hydrogel product via high-energy sterilization procedures, the at least one free radical absorber component preventing significant degradation of the hydrogel component.
19. The method for producing as defined in claim 11, wherein:  
combining into a mixture the gel component and the at least one free radical absorber component comprises combining about 2.1% by weight gel component powder with about 1.86% by weight potassium metabisulfite powder and about 0.025% by weight ascorbic acid; and  
hydrating the mixture to form the hydrogel solution comprises hydrating the mixture with about 0.95% by weight isopropyl alcohol and about 95.07% by weight deionized water.
20. A cap for an ultrasound probe, comprising:  
a body defining a cavity into which a portion of an ultrasound probe is received; and  
a ruggedized hydrogel insert operably attached to the cap body, the hydrogel insert comprising:  
a gel component including carrageenan gum and konjac gum;  
isopropyl alcohol;  
deionized water; and  
a free radical absorber component for absorbing free radicals produced when the hydrogel is subjected to a high-energy sterilization procedure, the free radical absorber component including at least one of potassium metabisulfite and ascorbic acid.
21. The cap as defined in claim 20, wherein the free radical absorber component includes both potassium metabisulfite and ascorbic acid.

22. An ultrasound probe, comprising:  
a body including a transducer; and  
a ruggedized hydrogel product operably attached to the cap body, the hydrogel product comprising:  
a gel component;  
isopropyl alcohol;  
deionized water; and  
a free radical absorber component for absorbing free radicals produced when the hydrogel is subjected to a high-energy sterilization procedure.
23. The probe as defined in claim 22, wherein the free radical absorber component includes at least one of potassium metabisulfite and ascorbic acid and wherein the gel component includes a gum component.
24. The probe as defined in claim 22, wherein the probe is a flexible pancake probe and wherein the hydrogel product is slab-shaped and positioned on a bottom surface of the pancake probe.
25. The probe as defined in claim 24, wherein the pancake probe includes a flexible outer perimeter that bounds a flexible transducer, the transducer including polyvinylidene fluoride.
26. The probe as defined in claim 25, wherein the transducer is segmented into a plurality of discrete transducer elements.



**FIG. 1**

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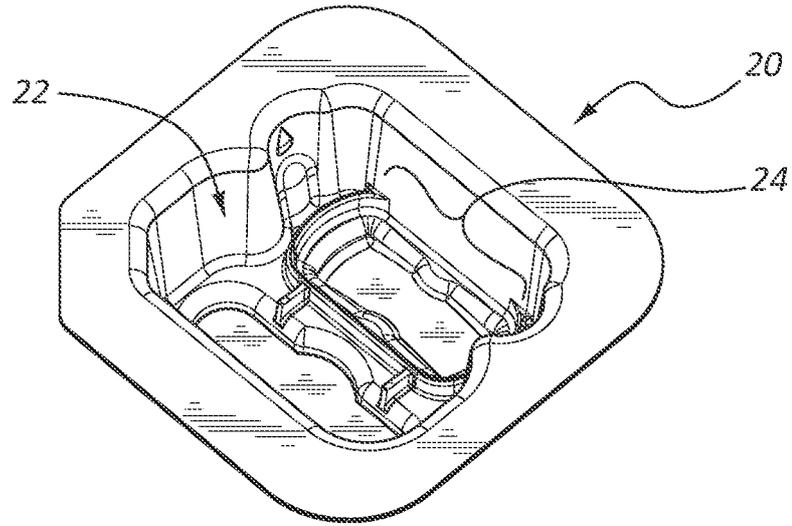


FIG. 2A

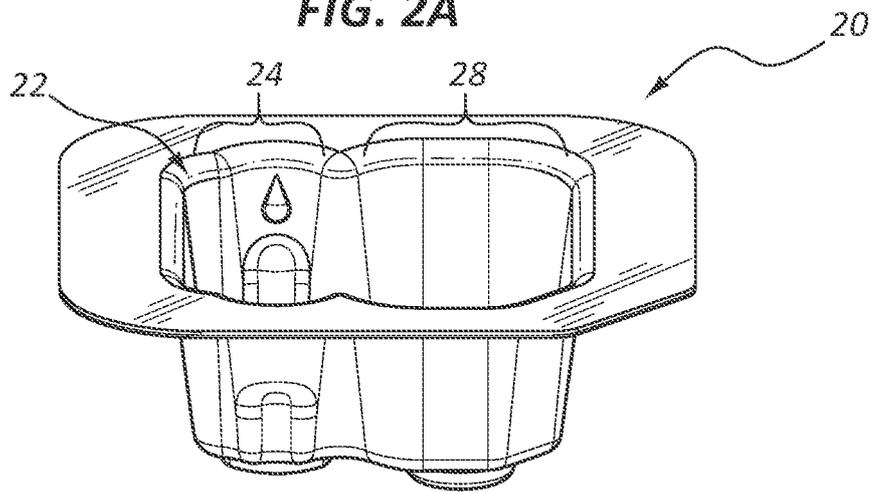


FIG. 2B

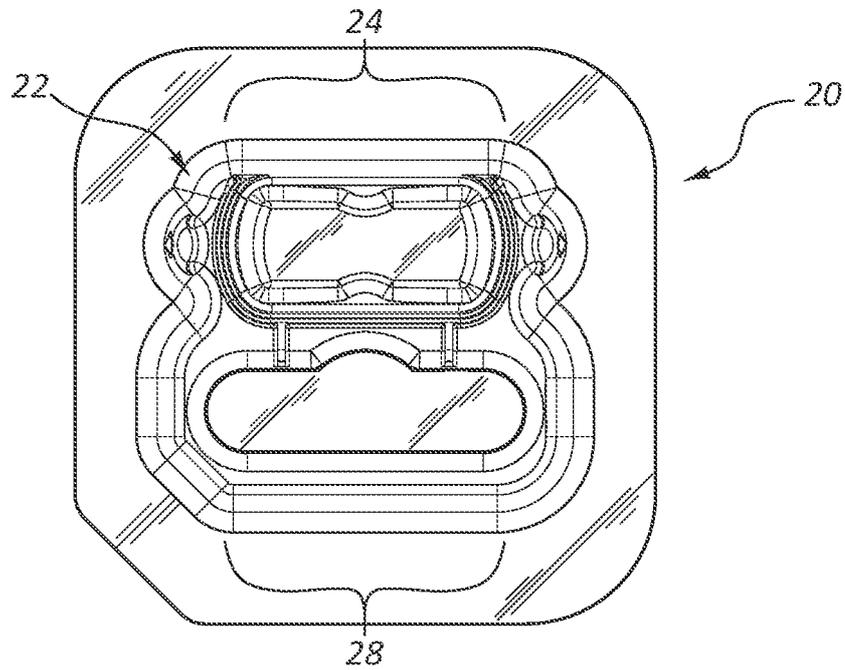


FIG. 2C

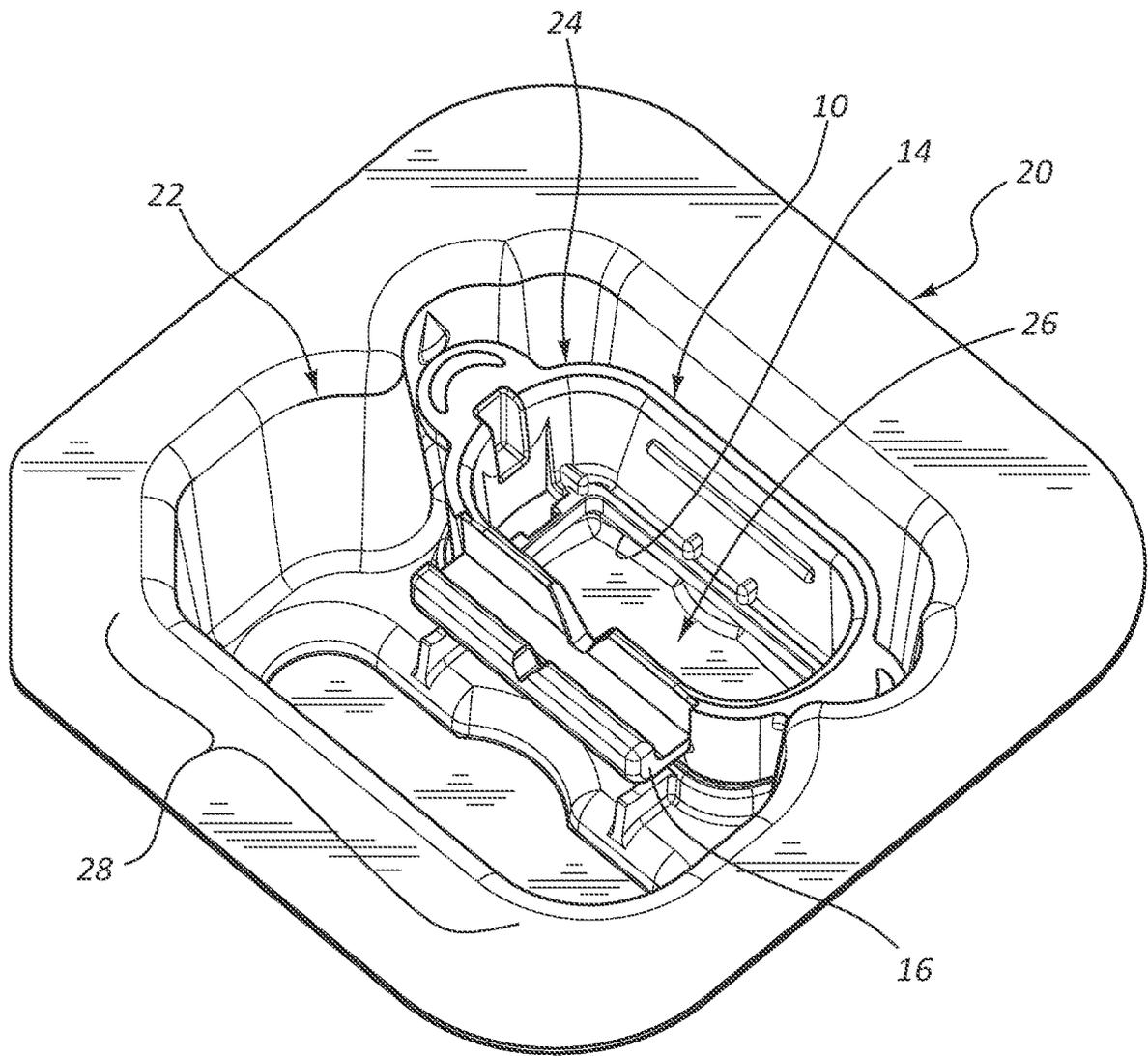


FIG. 3

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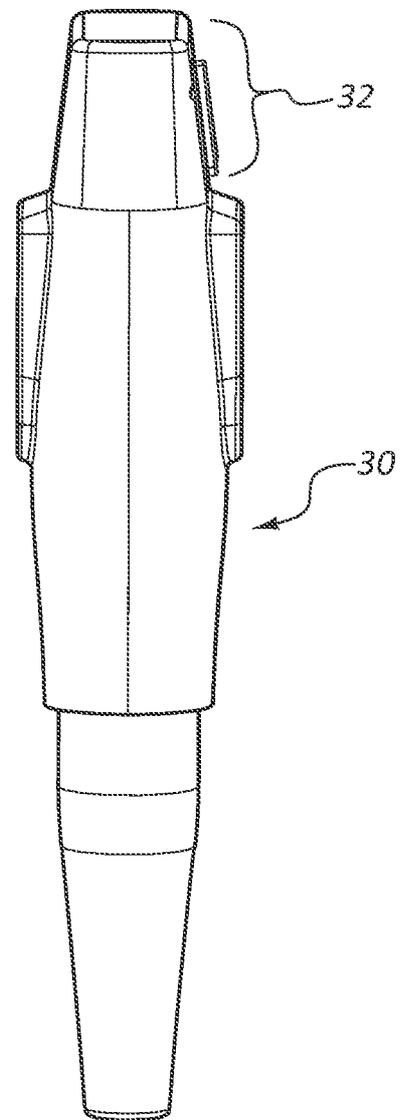
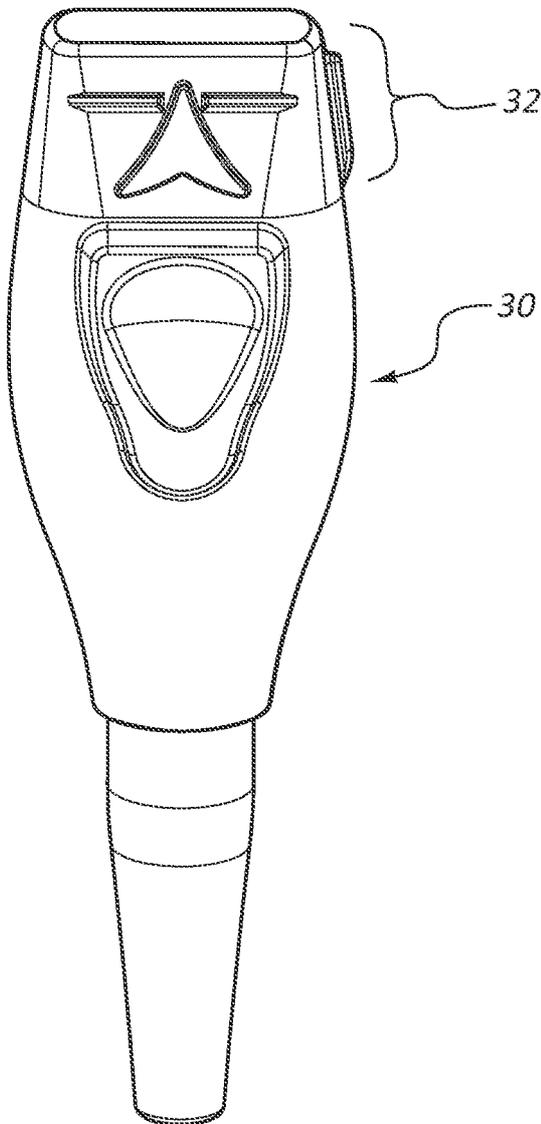
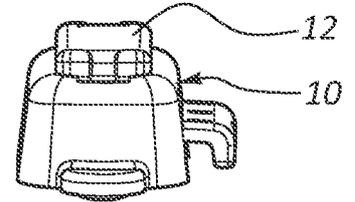
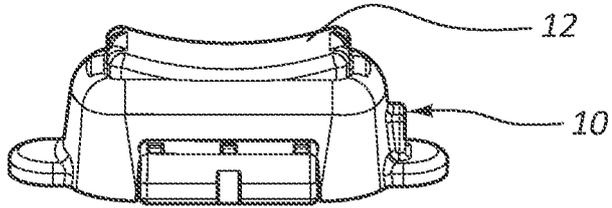


FIG. 4A

FIG. 4B

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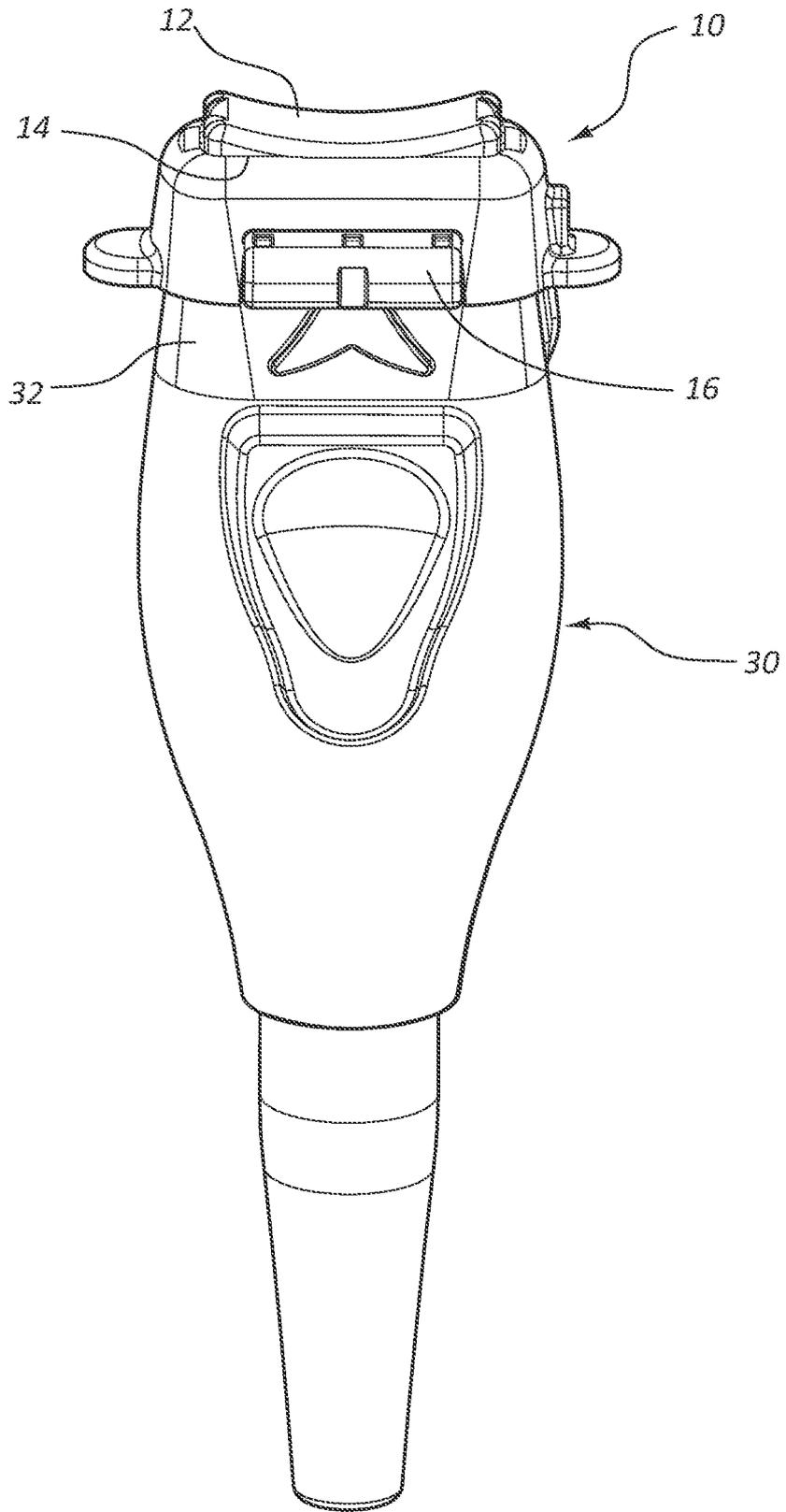
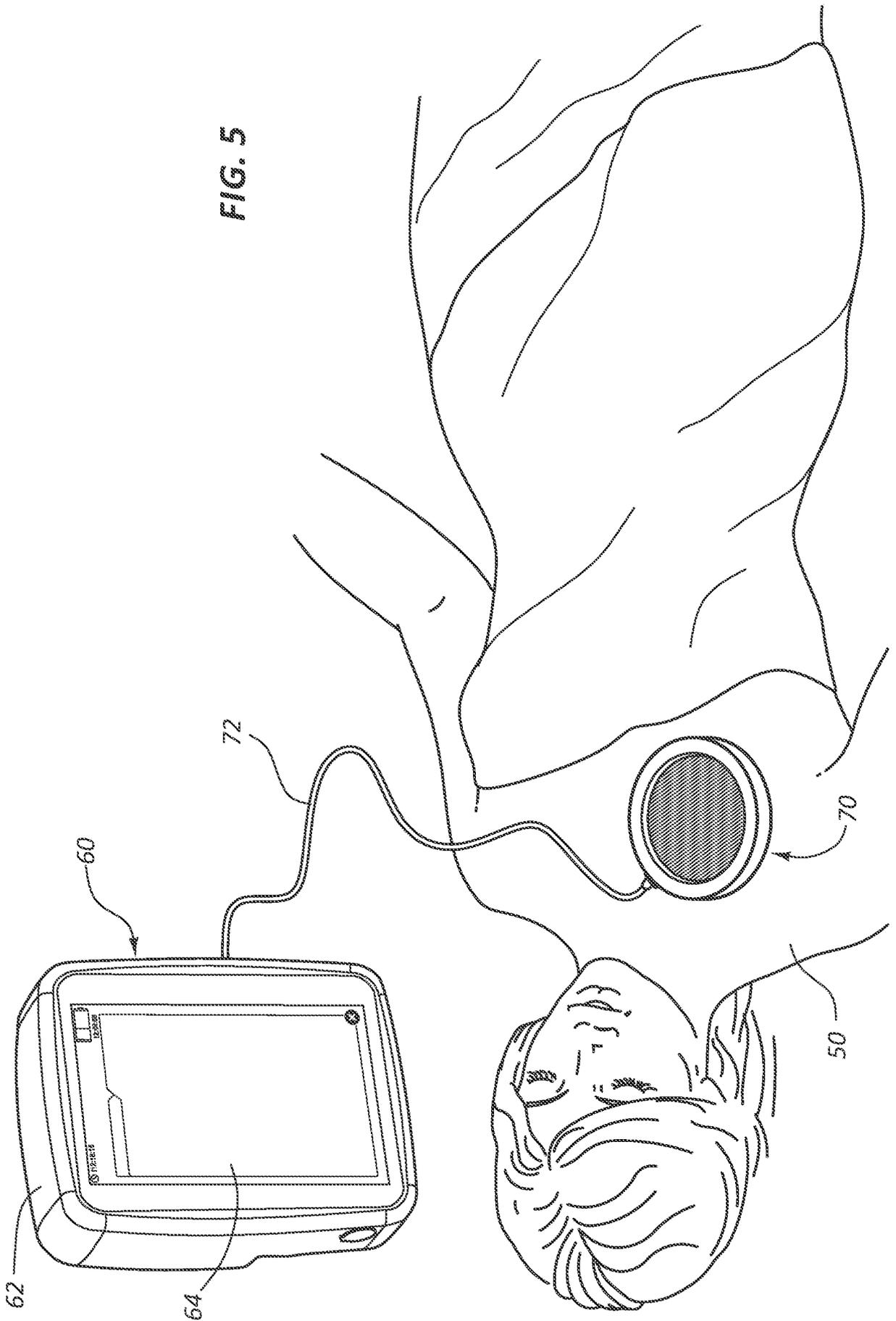


FIG. 4C

FIG. 5



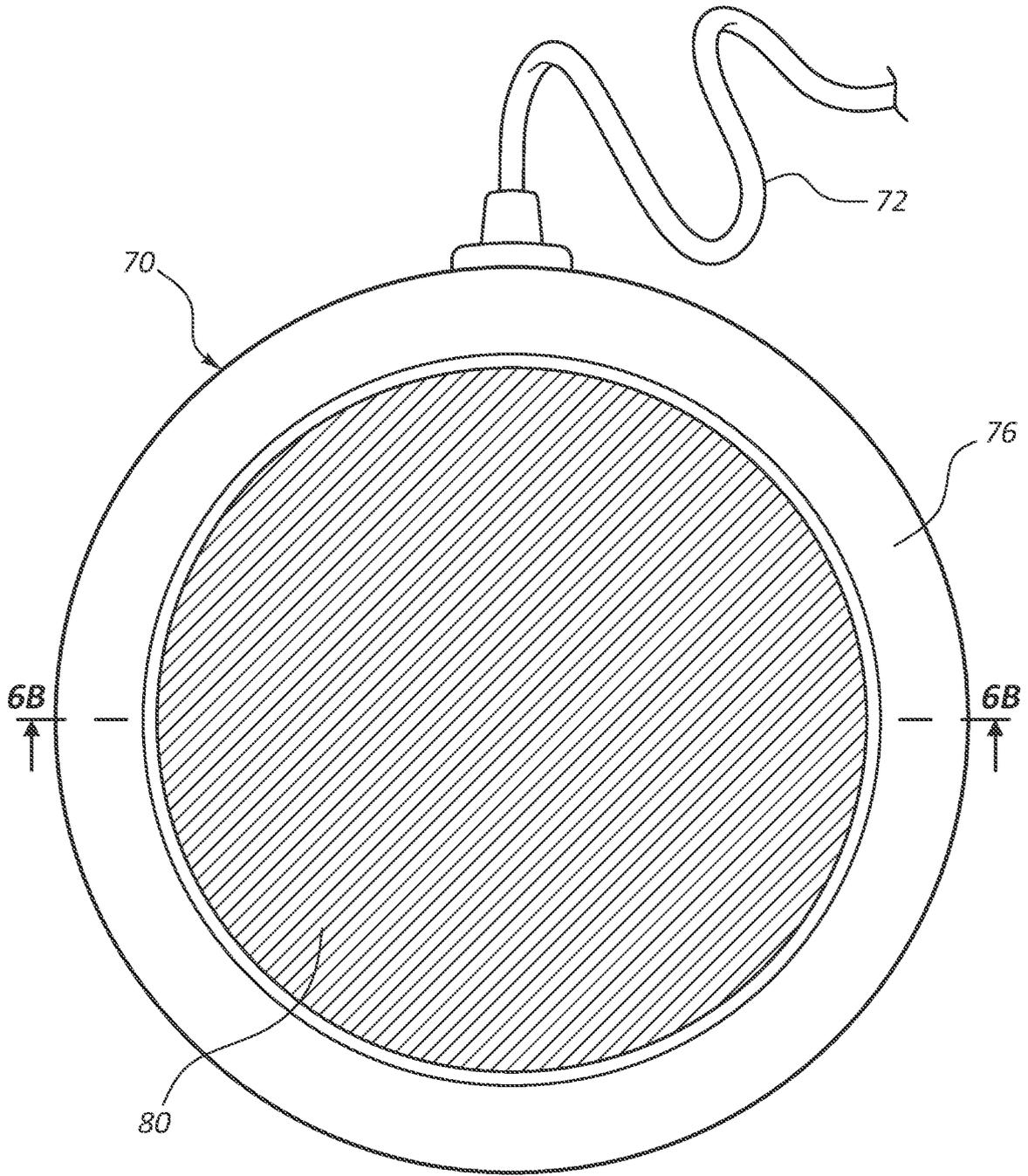


FIG. 6A

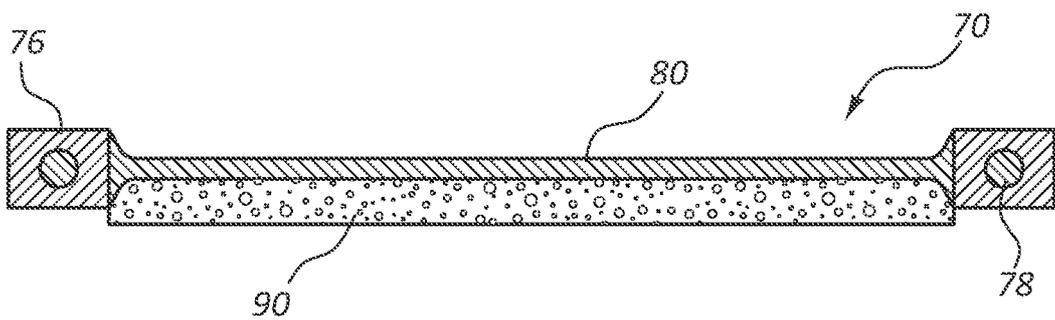


FIG. 6B

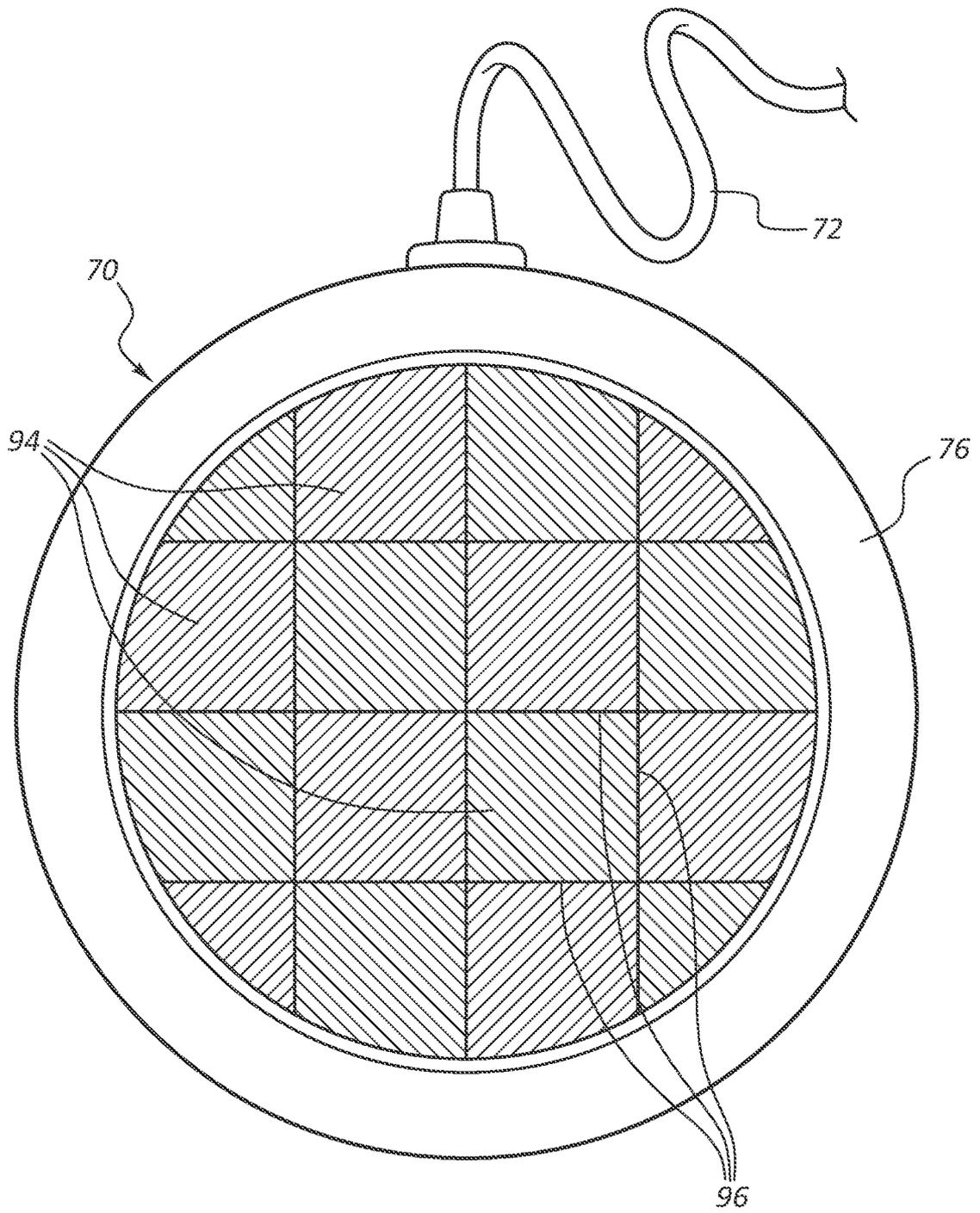


FIG. 7

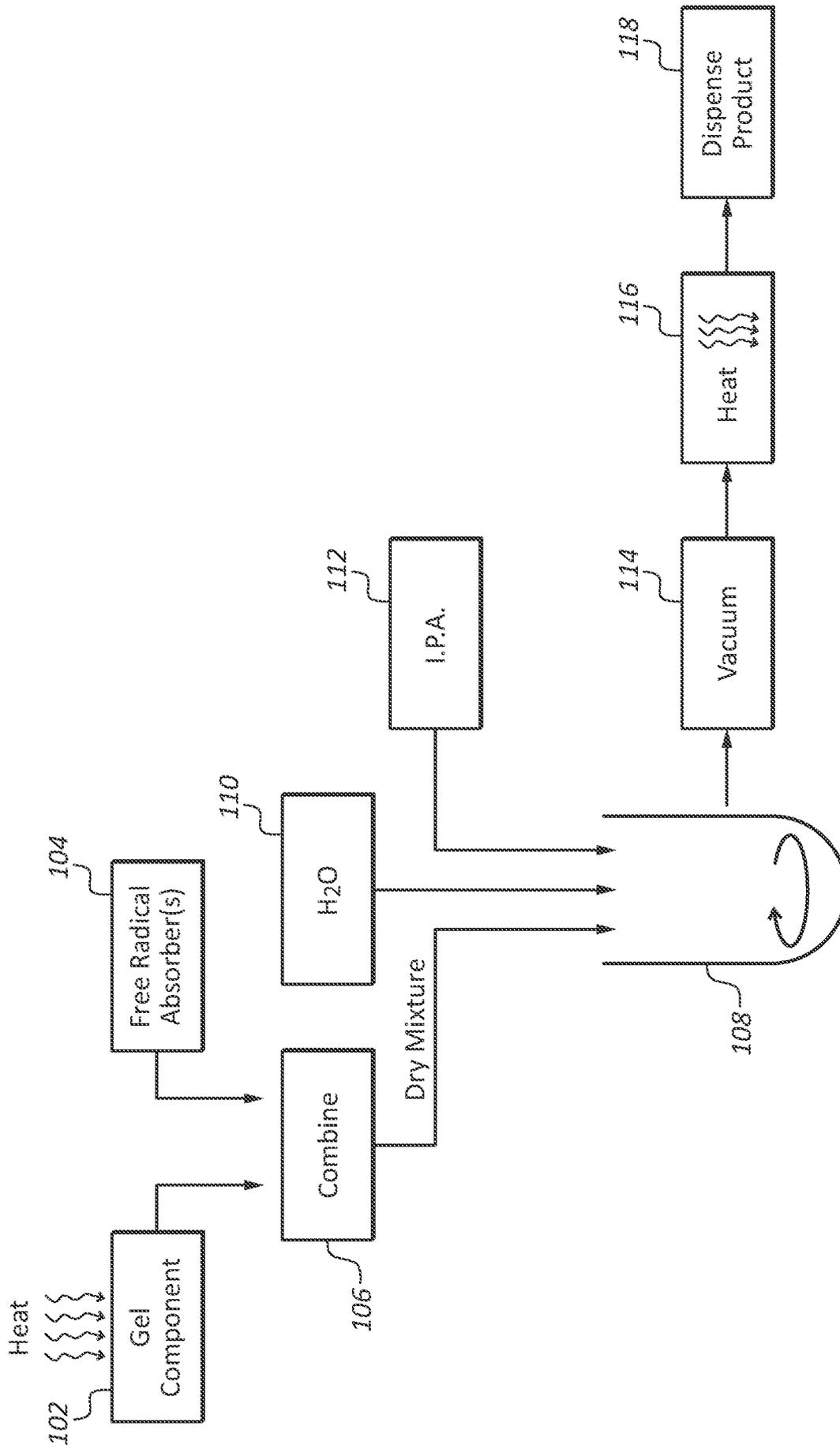


FIG. 8

**INTERNATIONAL SEARCH REPORT**

International application No.

PCT/US 12/63956

**A. CLASSIFICATION OF SUBJECT MATTER**  
 IPC(8) - A61N 7/00; A61B 8/00; G01N 29/00 (2013.01)  
 USPC - 600/437, 600/459; 607/152; 73/644  
 According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**  
 Minimum documentation searched (classification system followed by classification symbols)  
 IPC(8) - A61N 7/00; A61 B 8/00; G01 N 29/00 (2013.01 )  
 USPC - 600/437, 600/459; 607/152; 73/644

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
 PatBase; PubWEST (PGPB, USPT, USOC, EPAB, JPAB); Google Patents, Google Scholar: hydrogel; rugged\*; potassium chloride; calcium chloride; carrageenan; konjac; locust bean; gum; water; deionized water; DI; isopropyl alcohol; isopropanol; steriliz\*; high energy; gamma beam; electron beam; absorb \*; radical\*; ascorbic acid; vitamin C

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ---- Y	US 5,540,033 A (FOX, et al.) 30 July 1996 (30.07.1996) Table 1; Abstract; col 1, ln 34 to col 2, ln 25; col 2, ln 34 to col 3, ln 47; col 3, ln 66 to col 4, ln 61; col 8, ln 45-47; col 8, ln 65 to col 9, ln 30	1-3, 6-7 and 9-10 ----- 4-5 and 8
Y	US 2003/0149359 A1 (SMITH) 07 August 2003 (07.08.2003) Abstract; para [0011]-[0013], [0022]-[0023], [0027]	4
Y	US 2004/0231065 A1 (DANIEL, et al.) 25 November 2004 (25.11.2004) claims 6-8; abstract; para [0138]-[0139]	5
Y	US 2011/0171286 A1 (CECILE, et al.) 14 July 2011 (14.07.2011) Abstract; para [0024], [0034], [0043]	8
A	US 5,405,366 A (FOX, et al.) 11 April 1995 (11.04.1995) entire document	1-10
A	WO 2011/051406 A1 (RAU, et al.) 05 May 2011 (05.05.2011) entire document	1-10
A	US 2006/0188487 A1 (THOMAS, et al.) 24 August 2006 (24.08.2006) Abstract; para [0017]-[0018], [0062]-[0066], [0071]-[0072]	5

Further documents are listed in the continuation of Box C.

\* Special categories of cited documents:  
 "A" document defining the general state of the art which is not considered to be of particular relevance  
 "E" earlier application or patent but published on or after the international filing date  
 "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)  
 "O" document referring to an oral disclosure, use, exhibition or other means  
 "P" document published prior to the international filing date but later than the priority date claimed  
 "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  
 "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone  
 "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art  
 "&" document member of the same patent family

Date of the actual completion of the international search 12 March 2013 (12.03.2013)	Date of mailing of the international search report <b>01 APR 2013</b>
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/63956

**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

- 1.  Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
- 2.  Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
  
- 3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:  
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1 .

Group I: Claims 1-10, drawn to a ruggedized hydrogel product, comprising: a gel component; water for hydrating the gel component; and at least one free radical absorber component capable of absorbing free radicals produced when the hydrogel product is sterilized via one or more high energy sterilization procedures.

Group II: Claims 11-19, drawn to a method for producing a ruggedized hydrogel product capable of withstanding a high-energy sterilization procedure, the method comprising: combining into a mixture a gel component and at least one free radical absorber component; hydrating the mixture to form a hydrogel solution; and forming the hydrogel solution into a hydrogel product.

\*\*\*\*\*Continued in Supplemental  
Box\*\*\*\*\*

- 1.  As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
- 2.  As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
- 3.  As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
  
- 4.  No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:  
1-10

**Remark on Protest**

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

Continuation of BOX III - Observations where unity of invention is lacking:

Group III: Claims 20-26, drawn to a cap for an ultrasound probe, comprising: a body defining a cavity into which a portion of an ultrasound probe is received; and a ruggedized hydrogel insert operably attached to the cap body, the hydrogel insert comprising: a gel component including carrageenan gum and konjac gum; isopropyl alcohol; deionized water; and a free radical absorber component for absorbing free radicals produced when the hydrogel is subjected to a high-energy sterilization procedure, the free radical absorber component including at least one of potassium metabisulfite and ascorbic acid; AND An ultrasound probe, comprising: a body including a transducer; and a ruggedized hydrogel product operably attached to the cap body, the hydrogel product comprising: a gel component; isopropyl alcohol; deionized water; and a free radical absorber component for absorbing free radicals produced when the hydrogel is subjected to a high-energy sterilization procedure.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I-II do not include the inventive concept of a cap for an ultrasound probe, and/or an ultrasound probe, as required by Group III.

Groups I and III do not include the inventive concept of a method for producing a ruggedized hydrogel product, as required by Group II.

Group II does not include the inventive concept that water being hydrating agent, as required by Group I.

Groups I-III share the technical feature of a ruggedized hydrogel product, comprising: a gel component; a hydrating agent for hydrating the gel component; and at least one free radical absorber component capable of absorbing free radicals produced when the hydrogel product is sterilized via one or more high energy sterilization procedures.

Groups I and III share the technical feature of a ruggedized hydrogel product, comprising: a gel component; water for hydrating the gel component; and at least one free radical absorber component capable of absorbing free radicals produced when the hydrogel product is sterilized via one or more high energy sterilization procedures.

However, these shared technical features do not represent a contribution over the prior art, specifically, US 5,540,033 A to Fox et al. (hereinafter 'Fox') teaches a ruggedized hydrogel product (Abstract; col 3, ln 37-46; disclosing where the hydrogel is an extended-life wound dressing, electrode, or ultrasound coupling sheet; col 3, ln 66 to col 4, ln 9-A low area-density scrim such as non-woven polyethylene can be immersed into the cast mixture prior to irradiating to provide increased strength to the resulting hydrogel'), comprising:

- a gel component (col 2, ln 34 to col 3, ln 10; disclosing several polymers to produce the hydrogel, including PVP and PEO);

-water for hydrating the gel component (col 2, ln 34 to col 3, ln 10; col 8, ln 66 to col 9, ln 30; showing the amount of water within the aqueous hydrogel solution); and

--at least one free radical absorber component (col 1, ln 34 to col 2, ln 5; disclosing where a cross-linking inhibitor is included in the hydrogel product, preferably ascorbic acid) capable of absorbing free radicals produced when the hydrogel product is sterilized via one or more high-energy sterilization procedures (col 1, ln 34 to col 2, ln 25; col 4, ln 31-41; disclosing where the cross-linking inhibitor is capable of absorbing free radicals during a high-energy sterilization procedure ['ascorbic acid' is used in the Current Application as a free radical absorber according to Claim 7 of the Current Application.]).

As said shared technical features were known at the time of the invention, these shared technical feature cannot be considered special technical feature that would otherwise unify the groups.

Groups I-III therefore lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.